

73049-57

7/2/2014

1/8

UNIT STATES ENVIRONMENTAL PROTECTION AGENCY

JUL 02 2014

Ms. Jayne Walz
Regulatory Manager
Valent BioSciences Corporation
870 Technology Way
Libertyville, IL 60048-6316

Re: Valent BioSciences Corporation (Valent); VectoLex® WDG Biological Larvicide Water
Dispersible Granule
EPA Registration No. 73049-57
Minor Label and Formulation ("Fast Track") Amendment
Submissions Dated 04/04/2011, 06/23/2014, 06/25/2014, and 06/26/2014
Decision No. 448005

Dear Ms. Walz:

The U.S. Environmental Protection Agency (EPA) reviewed your request to amend the subject product registration, which included the following changes to the product label:

- 1) Correction of minor formatting inconsistencies and typographical errors.
2) Modification of the primary brand name.
3) Modification of the active ingredient name.
4) Addition of "Produced For" in front of Valent's name and address in accordance with 40 CFR § 156.10(c).
5) Replacement of "Net Contents" with "Net Weight" as VectoLex® WDG Biological Larvicide Water Dispersible Granule is a solid (Chapter 17, Section III of the EPA's Label Review Manual - Revised November 2012).
6) Addition of First Aid Statements and Hazards to Humans and Domestic Animals Statements for the inhalation route of exposure, given VectoLex® WDG Biological Larvicide Water Dispersible Granule's toxicity profile.

CONCURRENCES

Table with 8 columns and 3 rows (SYMBOL, URNAME, DATE) containing handwritten entries for 7511P, KAUSCH, and dates 06/30/2014, 7/1/14, 7/2/14.

Jayne Walz  
EPA Registration No. 73049-57

- 7) Modification of the following statement in the Hazards to Humans and Domestic Animals section (Chapter 7, Section III(D) of the EPA’s Label Review Manual – Revised July 2012) (changes emphasized):

APR 03 JUL

“Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet.”

- 8) Modification of the Environmental Hazards section as follows (Chapter 8, Section III(B) of the EPA’s Label Review Manual – Revised September 2012):

“Do not apply directly to treated, finished drinking water reservoirs or drinking water receptacles when the water is intended for human consumption.”

REPLACES

“Do not contaminate water when cleaning equipment or disposing of equipment washwaters.”

- 9) Removal of the following statement from the Directions for Use:

“Do not apply directly to treated finished drinking water reservoirs or drinking water receptacles.”

- 10) Adjustment of text in the Storage and Disposal Box to align with information presented in Chapter 13 of the EPA’s Label Review Manual (Revised July 2013) and to account for the intended packaging of the product.

- 11) Addition of the following statements to the Directions for Use (consistent with what is found on the labels of other registered Valent pesticide products with *Bacillus sphaericus* 2362, Serotype H5a5b, Strain ABTS 1743 as an active ingredient):

“VectoLex® WDG Biological Larvicide Water Dispersible Granule (hereafter referred to as VectoLex WDG) is a selective microbial insecticide for use against mosquito larvae in a variety of habitats. VectoLex WDG can be applied to areas that contain fish, other aquatic life and plants. VectoLex WDG can be applied to areas used by or in contact with humans, pets, horses, livestock, birds, or wildlife.”

- 12) Modification of several statements in the Directions for Use for clarification purposes (e.g., application instructions presented in ounces and pounds).

- 13) Addition of “To the extent consistent with applicable law” to two sentences in the Notice to User section to align with information presented in Chapter 12, Section IX of the EPA’s Label Review Manual (Revised November 2013).

3/8

Jayne Walz  
EPA Registration No. 73049-57

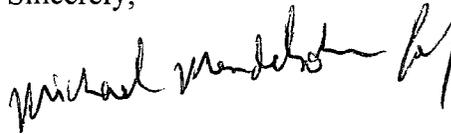
Additionally, you updated the confidential statement of formula (CSF) on file for VectoLex® WDG Biological Larvicide Water Dispersible Granule. There is now only one valid CSF for this product registration: a basic formulation dated June 26, 2014. All previously accepted VectoLex® WDG Biological Larvicide Water Dispersible Granule CSFs have been superseded by the aforementioned CSF.

All the changes referred to above, submitted in connection with registration under section 3(c)(5) of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), are acceptable provided that you submit two (2) copies of your final printed labeling before you release the product for shipment. Refer to the A-79 enclosure for further description of final printed labeling.

Your release for shipment of the product bearing the amended labeling constitutes acceptance of these conditions. If you have any questions regarding this letter, please contact Ms. Jeannine Kausch of my staff by telephone (703-347-8920) or email ([kausch.jeannine@epa.gov](mailto:kausch.jeannine@epa.gov)).

A stamped, accepted copy of the label is enclosed for your records.

Sincerely,



Kimberly Nesci, Chief  
Microbial Pesticides Branch  
Biopesticides and Pollution  
Prevention Division (7511P)

Enclosures (2):

- VectoLex® WDG Biological Larvicide Water Dispersible Granule Stamped, Accepted Label
- A-79 Enclosure

4/8

VECTOLEX® WDG  
BIOLOGICAL LARVICIDE  
WATER DISPERSIBLE GRANULE

Active Ingredient:

<i>Bacillus sphaericus</i> 2362, Serotype H5a5b, Strain ABTS 1743 fermentation solids, spores and insecticidal toxins.....	51.2% w/w
Other Ingredients.....	48.8% w/w
Total.....	100.0% w/w

Potency: This product contains 650 BsITU/mg or 0.299 Billion BsITU/lb.

The percent active ingredient does not indicate product performance and potency measurements are not federally standardized.

KEEP OUT OF REACH OF CHILDREN  
CAUTION

ACCEPTED

JUL 02 2014

Produced For:  
Valent BioSciences Corporation  
870 Technology Way  
Libertyville, IL 60048

Under the Federal Insecticide, Fungicide,  
and Rodenticide Act, as amended, for  
the pesticide registered under  
EPA Reg. No. 73049-57

EPA Reg. No. 73049-57  
EPA Est. No. 33762-IA-1

Batch Code: \_\_\_\_\_

Net Weight:

FIRST AID	
If in eyes	<ul style="list-style-type: none"> <li>◦ Hold eye open, and rinse slowly and gently with water for 15 - 20 minutes.</li> <li>◦ Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye.</li> <li>◦ Call a poison control center or doctor for treatment advice.</li> </ul>
If inhaled	<ul style="list-style-type: none"> <li>◦ Move person to fresh air.</li> <li>◦ If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably by mouth-to-mouth if possible.</li> <li>◦ Call a poison control center or doctor for further treatment advice.</li> </ul>
HOT LINE NUMBER	
Have the product container or label with you when calling a poison control center or doctor, or going for treatment. You may also contact 1-877-315-9819 (24 hours) for emergency medical treatment and/or transport emergency information. For all other information, call 1-800-323-9597.	

5/8

**PRECAUTIONARY STATEMENTS  
HAZARDS TO HUMANS AND DOMESTIC ANIMALS  
CAUTION**

Causes moderate eye irritation. Harmful if inhaled. Avoid contact with eyes or clothing and breathing dust or spray mist. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet. Remove and wash contaminated clothing before reuse.

Mixer/loaders and applicators not in enclosed cabs or aircraft must wear a dust/mist filtering respirator meeting NIOSH standards of at least N-95, R-95, or P-95. Repeated exposure to high concentrations of microbial proteins can cause allergic sensitization.

**ENVIRONMENTAL HAZARDS**

Do not apply directly to treated, finished drinking water reservoirs or drinking water receptacles when the water is intended for human consumption.

**DIRECTIONS FOR USE**

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

**CHEMIGATION**

Do not apply this product through any type of irrigation system.

**STORAGE AND DISPOSAL**

Do not contaminate water, food, or feed by storage or disposal.

**Pesticide Storage:**

Store in cool [59-86° F (15-30° C)], dry place.

**Pesticide Disposal:**

Wastes resulting from the use of this product must be disposed of on site or at an approved waste disposal facility.

**Container Handling:**

Nonrefillable container. Do not reuse or refill this container. Triple rinse container (or equivalent) promptly after emptying. Triple rinse as follows: Empty the remaining contents into application equipment or a mix tank. Fill the container ¼ full with water and recap. Shake for 10 seconds. Pour rinsate into application equipment or a mix tank, or store rinsate for later use or disposal. Drain for 10 seconds after the flow begins to drip. Repeat this procedure two more times. Then, offer for recycling, if available or puncture and dispose of in a sanitary landfill, or by incineration, or, if allowed by state and local authorities, by burning. If burned, stay out of smoke.

### APPLICATION DIRECTIONS

VectoLex® WDG Biological Larvicide Water Dispersible Granule (hereafter referred to as VectoLex WDG) is a selective microbial insecticide for use against mosquito larvae in a variety of habitats. VectoLex WDG can be applied to areas that contain fish, other aquatic life and plants. VectoLex WDG can be applied to areas used by or in contact with humans, pets, horses, livestock, birds, or wildlife.

Do not apply when wind speed favors drift beyond the area of treatment.

I. For control of mosquito larvae species\* in the following non-crop sites:

<u>Habitats</u>	<u>Application Rate Range</u>
<b>Wastewater:</b> Sewage effluent, sewage lagoons, oxidation ponds, septic ditches, animal waste lagoons and impounded wastewater associated with fruit and vegetable processing	0.5-1.5 lbs/acre (8-24 oz/acre)
<b>Stormwater/Drainage Systems:</b> Storm sewers, catch basins, drainage ditches, retention ponds, detention ponds and seepage ponds	0.5-1.5 lbs/acre (8-24 oz/acre)
<b>Marine/Coastal Areas:</b> Salt marshes, mangroves and estuaries	0.5-1.5 lbs/acre (8-24 oz/acre)
<b>Water Bodies:</b> Natural and manmade aquatic sites such as lakes, ponds, rivers, canals and streams	0.5-1.5 lbs/acre (8-24 oz/acre)
<b>Dormant Rice Fields:</b> Impounded water in dormant rice fields (For application ONLY during the interval between harvest and preparation of the field for the next cropping cycle)	0.5-1.5 lbs/acre (8-24 oz/acre)

II. For control of mosquito larvae species\* in the following agricultural/crop sites where mosquito breeding occurs:

<u>Habitats</u>	<u>Application Rate Range</u>
Rice, pastures/hay fields, orchards, citrus groves and irrigated crops	0.5-1.5 lbs/acre (8-24 oz/acre)

Use higher application rates (1 - 1.5 lbs/acre or 16 – 24 oz/acre) in areas where extended residual control is necessary, or in habitats having deep water or dense surface cover.

Apply uniformly by aerial or conventional ground application equipment. Reapply as needed after 1-4 weeks.

\*Mosquito species effectively controlled by VectoLex WDG:

- Culex* spp.
- Aedes vexans*
- Ochlerotatus melanimon*      (*Aedes melanimon*)
- Ochlerotatus stimulans*      (*Aedes stimulans*)
- Ochlerotatus nigromaculis*      (*Aedes nigromaculis*)
- Psorophora columbiae*
- Psorophora ferox*
- Ochlerotatus triseriatus*      (*Aedes triseriatus*)
- Ochlerotatus sollicitans*      (*Aedes sollicitans*)
- Anopheles quadrimaculatus*
- Coquillettidia perturbans*

**GROUND AND AERIAL APPLICATION**

VectoLex WDG may be applied using conventional ground or aerial application equipment with quantities of water sufficient to provide uniform coverage of the target area. For application, first add the VectoLex WDG to water to produce a final spray mixture.

The amount of water needed for application will depend on weather, spray equipment, and mosquito habitat characteristics. For application, fill the mix tank or plane hopper with the desired quantity of water. **Start the mechanical or manual agitation to provide moderate circulation of water before adding VectoLex WDG.** Backpack and compressed air sprayers may be agitated by shaking after adding VectoLex WDG to the water in the sprayer. VectoLex WDG suspends readily in water and will stay suspended over normal application periods. Brief recirculation may be necessary if the final spray mixture has sat for several hours or longer. Do not mix more VectoLex WDG than can be used in a 48-hour period. **AVOID CONTINUOUS AGITATION OF THE FINAL SPRAY MIXTURE DURING SPRAYING.**

For ground application, apply 0.5-1.5 lbs or 8-24 oz (227-680 g) of VectoLex WDG in 5-100 gallons of water per acre using hand-pump, airblast, mist blower, or other spray equipment. For aerial application, apply 0.5-1.5 lbs or 8-24 oz (227-680 g) of VectoLex WDG per acre through fixed wing or helicopter aircraft equipped with either conventional boom and nozzle systems or rotary atomizers at a convenient dilution rate. For aerial application, apply 0.5-10 gal of the final spray mixture per acre to provide uniform coverage of the target area.

Avoiding spray drift at the application site is the responsibility of the applicator. The interaction of many equipment- and weather-related factors determines the potential spray drift. The applicator and treatment coordinator are responsible for considering all these factors.

Rinse and flush spray equipment thoroughly following each use.

Amount of VectoLex WDG needed to treat small areas:

Area to Treat	Application Rate of VectoLex WDG/Acre		
	0.5 lb (8 oz)	1 lb (16 oz)	1.5 lb (24 oz)
¼ Acre	0.125 lb (2 oz)	0.25 lb (4 oz)	0.375 lb (6 oz)
½ Acre	0.25 lb (4 oz)	0.5 lb (8 oz)	0.75 lb (12 oz)
10 Acres	5 lb (80 oz)	10 lb (160 oz)	15 lb (240 oz)
20 Acres	10 lb (160 oz)	20 lb (320 oz)	30 lb (480 oz)

**NOTICE TO USER**

To the extent consistent with applicable law, Seller makes no warranty, express or implied, of merchantability, fitness or otherwise concerning use of this product other than as indicated on this label. To the extent consistent with applicable law, User assumes all risks of use, storage or handling not in accordance with accompanying directions.

© 2014